UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NEXUS PHARMACEUTICALS, LLC, Plaintiff, v. LONG GROVE PHARMACEUTICALS, LLC, Defendant.	)	Civil Action No. 24-10444-MJJ

MEMORANDUM OF DECISION

January 13, 2025

JOUN, D.J.

Plaintiff Nexus Pharmaceuticals, LLC ("Nexus") brings a claim for false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(A)(1), against its competitor Long Grove Pharmaceuticals, LLC ("Long Grove"). Specifically, Nexus seeks relief for lost sales and customers in connection with its fluorescein drug product. Nexus alleges that Long Grove misled healthcare providers by making false statements on its website regarding a shortage of fluorescein, which Nexus alleges had the effect of diverting customers away from purchasing Nexus's fluorescein product and preventing Nexus from converting customers. Because Long Grove's statements regarding the fluorescein shortage concerned market conditions, and not the nature, characteristics, or qualities of either party's product, Nexus has failed to state a claim under the Lanham Act. For the reasons stated below, the Motion to Dismiss is GRANTED.

I. BACKGROUND

A. Relevant Facts

a. Regulatory Context Regarding The FDA's Approach To Drug Shortages

The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") charges the U.S. Food and Drug Administration ("FDA" or the "Agency") with promoting public health by ensuring that drugs are safe and effective, and taking appropriate action on the marketing of regulated products in a timely manner. 21 U.S.C. § 393(b). This includes authorization for the FDA to exercise regulatory flexibility and enforcement discretion as needed to mitigate drug shortages. 21 U.S.C. § 356c-1(a)(7). To implement the FDCA's mandate, the FDA "has worked cooperatively with manufacturers to prevent or mitigate shortages [of regulated drug products] by . . . adopting a flexible approach to drug manufacturing and importation regulations where appropriate." Executive Order No. 13588 (Oct. 31, 2011), 76 Fed. Reg. 68295, at Sec. 1.[1] And at times, the FDA has temporarily exercised "regulatory flexibility and discretion" to "help[] to alleviate a drug shortage and to ensure access to treatment options for patients in critical need." FDA, Tenth Annual Report on Drug Shortages for Calendar Year 2022, at 12. If the FDA approves a new drug product addressing an existing shortage, the Agency may exercise its enforcement discretion by allowing manufacturers authorized to sell an unapproved drug to continue doing so for a grace period after the shortage ends. *See, e.g., FDA, Marketed Unapproved Drugs—Compliance Policy Guide*: Sec. 440.100, Marketed New Drugs without

[1] The Court takes judicial notice of this and other cited FDA regulatory materials, which are publicly available. *See, e.g., Torrens v. Lockheed Martin Servs. Grp., Inc.*, 396 F.3d 468, 473 (1st Cir. 2005) (noting courts may take "judicial notice of the existence of government records"); *Pietrantoni v. Corcept Therapeutics Inc.*, 640 F. Supp. 3d 197, 205 (D. Mass. 2022) ("this Court on several occasions has taken judicial notice of information on the FDA's website" at the motion to dismiss stage); *In re Vertex Pharms. Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (taking judicial notice of FDA policy in considering motion to dismiss).

Approved NDAs or ANDAs (Sept. 2011), at 7 ("When a company obtains approval to market a product that other companies are marketing without approval, FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (e.g., seizure or injunction) against marketed unapproved products of the same type.").

b. Long Grove Purchases And Begins Selling Akorn's Fluorescein Drug

In August 2008, the FDA approved a New Drug Application by Akorn, Inc. ("Akorn") for AK-FLUOR (Fluorescein Injection). [Doc No. 1 at ¶¶ 5, 29]. Fluorescein is a drug product used as part of a diagnostic angiography or angioscopy of the retina and iris vasculature, which enables X-ray-like images of veins. [*Id.* at ¶ 4]. In early 2023, Akorn filed for bankruptcy and stopped manufacturing AK-FLUOR. [*Id.* at ¶¶ 5–6, 30–31]. The nationwide supply of fluorescein sodium injection then became low, with the FDA identifying a shortage in April 2023. [*Id.* at ¶¶ 6, 33; Doc No. 1-3 at 2; Doc No. 1-4 at 2]. In June 2023, Long Grove bought the AK-FLUOR new drug application and the remaining AK-FLUOR inventory from Akorn's bankruptcy proceeding. [Doc No. 1 at ¶¶ 6, 31–32]. Given the shortage of fluorescein, the FDA exercised its enforcement discretion to permit Long Grove to sell Akorn's old stock of AK-FLUOR. [*Id.* at 1 ¶¶ 7, 9, 34; Doc No. 1-3 at 2].

Consistent with its regulatory authority, the FDA required Long Grove to draft and disseminate a "Dear Healthcare Professional" Letter ("DHP Letter"), which the FDA also posted on its website,[2] to ensure accurate and complete information reached the market about the AK-FLUOR drug. *See* FDA, *UPDATE—Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown* (May 4, 2023)

[2] *See* https://www.fda.gov/media/173588/download.

("Products not included in the press are continuing to be monitored under a Quality Program and will remain on the market," including AK-FLUOR supply).[3] The DHP Letter stated:

> Due to the current shortage of AK-FLUOR (fluorescein injection, USP) 10% and 25% in the United States (U.S.) market, Long Grove Pharmaceuticals, LLC ("Long Grove Pharmaceuticals") is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug.

[Doc No. 1-1 at 2]. The letter also stated that "[e]ffective immediately," Long Grove would distribute the "existing inventory manufactured by Akorn prior to closing to address this critical drug shortage." [*Id.*].

In accordance with FDA guidance, Long Grove published the DHP Letter on its website. [Doc. No. 1 at ¶¶ 8, 40]; 21 C.F.R. § 200.5; FDA, *Guidance for Industry: Dear Health Care Provider Letters: Improving Communication of Important Safety Information*, at 1 (2014).[4] And Long Grove reiterated the language from the DHP Letter on its website:

> Fluorescein Injection, USP is currently impacted by a supply shortage resulting from Akorn Pharmaceuticals' exit from the U.S. market. To ensure the consistent availability of Fluorescein Injection, USP prior to its relaunch as a Long Grove Pharmaceuticals product, Long Grove Pharmaceuticals has reached a distribution agreement with the FDA Office of Drug Shortages through the Regulatory Discretion process.

[Doc No. 1-3 at 2–3; Doc. No. 1 at ¶ 42].

c. <u>Nexus Receives FDA Approval For Its Own Fluoresceine Drug Product</u>

In September 2023, Nexus obtained FDA approval to market a generic version of Akorn's fluorescein sodium injection. [*Id.* at ¶¶ 11, 37–38]. No later than December 5, 2023, the FDA updated its Drug Shortages database to declare the shortage of fluorescein sodium injection

[3] *Available at* https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry#recall-announcement.

[4] *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dear-health-care-provider-letters-improving-communication-important-safety-information.

"[r]esolved." [*Id.* at ¶¶ 3, 12, 46; Doc No. 1-4 at 2]. As of December 5, 2023, the FDA listed fluorescein products of the following companies as available: Long Grove, Nexus, and Alcon. [Doc. No. 1-4 at 2-3].

After the FDA's December 5, 2023 update that the fluorescein shortage had been resolved, Long Grove continued to distribute and advertise AK-FLUOR with statements that a fluorescein shortage existed. [Doc. No. 1 at ¶¶ at 7–8, 13, 35, 41–44, 46–47].[5] Specifically, Long Grove maintained the Dear Healthcare Letter on its website and made references to a "supply shortage" on its website (the "shortage statements"). [*Id.* at ¶¶ 43, 46-47]. Nexus requested Long Grove to cease marketing and selling the AK-FLUOR product because the drug shortage had been declared resolved by the FDA, but Long Grove refused. [*Id.* at ¶¶ 51–52]. Long Grove maintains that it had permission from the FDA, pursuant to its drug shortage authority, to continue selling AK-FLUOR even after the shortage was resolved. [Doc. No. 16 at 7].

B. Nexus's Claims And Procedural History

Nexus maintains that Long Grove's shortage statements created a false impression that the fluorescein shortage continued after December 5, 2023, misleading customers to believe that Nexus' fluorescein product was not available and that only Long Grove could provide fluorescein. [*Id.* at ¶¶ 45, 48–49]. As a result, Nexus alleges that it lost customers to Long Grove. [*Id.* at ¶¶ 13, 27, 49–50]. Nexus also alleges that "[b]ecause Long Grove bought AK-FLUOR product from a bankrupt company, with a drug that was stored in conditions unknown to Nexus

[5] The drug shortage statements are no longer on Long Grove's website. [Doc No. 16 at 23 n. 13]. Although neither party has identified exactly when the shortage statements were removed from Long Grove's website, Plaintiff alleges that Long Grove removed the shortage statements from its website "after the Complaint was filed" on February 23, 2024, approximately 3 months after the FDA announced that the shortage was resolved. [Doc No. 24 at 7].

or the public," Long Grove "undercut[]" the price of its product due to the short expiration date of that product. [*Id.* at ¶¶ 13-14].

On February 23, 2024, Nexus filed this action, bringing a Lanham Act claim for unfair competition and false advertising against Long Grove (Count I). [Doc. No. 1]. Nexus seeks a declaratory judgment that Long Grove violated Section 43(a) of the Lanham Act. [*Id.* at 12]. Nexus also seeks actual damages due to "Long Grove's misrepresentations and pricing to exploit a supposed shortage that no longer exists," citing at least one customer that had purchased the Nexus fluorescein product but later informed Nexus that it was "switching to Long Grove's AK-FLUOR product." [*Id.* at 12; ¶¶ 18, 27].[6] On April 9, 2024, Long Grove filed a motion to dismiss the complaint for failure to state a claim and accompanying memorandum of law. [Doc. Nos. 15, 16]. Nexus filed its opposition to the motion on April 23, 2024. [Doc. No. 24]. Long Grove filed its reply on April 30, 2024. [Doc. No. 25]. A hearing on the motion was held on July 10, 2024.

II. LEGAL STANDARD

In evaluating a motion to dismiss for failure to state a claim, the Court must determine whether a complaint contains enough factual allegations to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In conducting this review, the Court "ignores statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action elements, then takes

[6] Nexus's Complaint also seeks preliminary injunctive relief and permanent injunctive relief. [Doc No. 1 at 12]. Nexus's request for injunctive relief is denied as moot because the drug shortage statements are no longer on Long Grove's website. See *supra* n. 5; *CCBN.com, Inc. v. c-call.com, Inc.*, 73 F. Supp. 2d 106, 115 (D. Mass. 1999) (Dismissing Lanham Act false advertising claim and denying request for injunctive relief as moot after defendant removed allegedly false statement from website).

the complaint's well-pled (i.e., non-conclusory, non-speculative) facts as true, drawing all reasonable inferences in the pleader's favor, and sees if they plausibly narrate a claim for relief." *Sonoiki v. Harvard Univ.*, 37 F.4th 691, 703 (1st Cir. 2022) (cleaned up). "[G]auging a pleaded situation's plausibility is a context-specific job that compels [the Court] to draw on [its] judicial experience and common sense." *Id.*

III. ANALYSIS

Long Grove makes multiple arguments in support of its Motion to Dismiss. First, Long Grove argues that Nexus's false advertising claim should more properly be characterized as a challenge to Long Grove's conduct in marketing, selling, and pricing its Akorn product. [Doc. No. 16 at 8]. Specifically, Long Grove asserts that Nexus is actually "challeng[ing] Long Grove's compliance with FDA regulatory law under the framework of the FDCA," under which there is no private right of action. [*Id.* at 9]. Second, Long Grove argues that "the Lanham Act cannot supply a basis for relief from a statement that FDA expressly mandated a manufacturer to make." [*Id.* at 13]. Third, Long Grove argues that even if Nexus's claim can be brought as a false advertising claim under the Lanham Act, the shortage statements fail to satisfy the elements required to state a Lanham Act false advertising claim. This Court agrees.

As explained below, the Court need not reach whether the Lanham Act is preempted by the FDCA or whether the Lanham Act can provide relief for statements permitted by the FDA, because Nexus cannot meet its burden of pleading, under the Lanham Act, that the shortage statements relate to either party's product.

A. The Lanham Act Requires That A False Advertising Statement Actually Relates To A Party's Product

> To prove a Lanham Act claim for unfair competition and false advertising, a plaintiff must demonstrate that (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement ***about his own or another's product***;

> (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Azurity Pharms., Inc. v. Edge Pharma, LLC, 45 F.4th 479, 486 (1st Cir. 2022) (emphasis added) (citing *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 310–11 (1st Cir. 2002). The Lanham Act requires that the alleged falsehood be related to plaintiff's "own or another's product." *Azurity*, 45 F.4th at 486. This means that the false advertising—here, the shortage statements—must "misrepresent[] the characteristics of the good *itself*—such as its properties or capabilities." *Williams-Sonoma, Inc. v. Wayfair Inc.*, 652 F. Supp. 3d 216, 223–24 (D. Mass. 2023) (cleaned up) (emphasis added).

B. The Shortage Statements Do Not Relate To Either Party's Fluorescein Product

The shortage statements do not refer to any inherent quality or characteristic of either party's fluorescein drug product, and thus the first element of a Lanham Act claim for false advertising and unfair competition is not met. Here, although Nexus takes issue with Long Grove discounting the pricing of its Akorn fluorescein product given its shorter expiration date, Nexus does not allege that Long Grove made a false or misleading statement about the actual age of the fluorescein drug or the quality of the fluorescein drug itself. *See, e.g.*, *Energizer, LLC v. MTA Trading, Inc.*, No. 20-cv-1583, 2021 WL 2453394, at *5 (E.D.N.Y. June 16, 2021) (holding that plaintiff adequately alleged statements that batteries were "new," when they were in fact not, were statements about the "inherent qualit[ies] or characteristic[s] of the product"); *Coca-Cola Co. v. Tropicana Prods.*, 690 F.2d 312, 318 (2d Cir. 1982) (holding that "the claim that [the

defendant's orange juice] contains only fresh-squeezed, unprocessed juice is clearly a misrepresentation as to that product's inherent quality or characteristic").

In *Williams-Sonoma*, for example, the plaintiff, Williams-Sonoma, alleged that Wayfair falsely advertised furniture that looked identical to plaintiff's furniture as exclusively available "only at Wayfair," "a Wayfair exclusive collection," and as to some products, "looks you'll only find at Wayfair." 652 F. Supp. 3d at 220. There, the plaintiff argued that these "false and misleading representations are material because they are likely to influence the purchasing decisions of the target consumers" and they "have a tendency to deceive target consumers." *Id.* at 221. The court held that plaintiff did not state a Lanham Act false advertising claim because "Wayfair's statements do not relate to the properties, capabilities, or characteristics of the goods. These statements of exclusivity more closely relate to misrepresentations about the *origin* of goods and are not cognizable under Section 43(a)(1)(B)." *Id.* at 224 (emphasis added).

As in *Williams-Sonoma*, Long Grove argues that the shortage statements in this case relate to "supply and demand phenomena," and "market conditions surrounding fluorescein that led FDA to exercise its enforcement discretion" rather than any inherent quality or characteristic of either party's fluorescein drug product. [Doc. No. 16 at 21; Doc. No. 25 at 7-8]. Nexus, however, argues that *Williams-Sonoma* does not apply because that case "was not about supply and demand phenomena." [Doc. No. 24 at 13]. But Nexus does not provide any persuasive support that statements regarding supply and demand phenomena are statements related to a product's inherent quality or characteristic for the purposes of a Lanham Act claim. Further, Nexus' allegations regarding the shortage statements are not entirely dissimilar from the statements that were rejected in *Williams-Sonoma*. Here, Nexus alleges that Long Grove's references to a shortage "falsely implies that Nexus's product does not exist or will imminently

not exist, and so it is a false statement about the nature and condition of Nexus's product." [*Id.* at 12]. Even if Long Grove had stated, as in *Williams-Sonoma*, that fluorescein was "only available at Long Grove" or "exclusively available at Long Grove," those more direct statements would still be insufficient because they do not relate to the inherent *quality* or *characteristic* of the product, as opposed to the market conditions (i.e., the existence or non-existence) of the product.

Other courts have similarly held that statements relating to the marketing *method* of a product are unrelated to the actual qualities or characteristics of the goods themselves under the Lanham Act. *See Abernathy & Closther, Ltd. v. E & M Advert., Inc.*, 553 F. Supp. 834, 837 (E.D.N.Y. 1982) (statements about an "exclusive T.V. offer" made "for the first time on T.V.," although appearing to be "patently false," did not relate to the "inherent quality or characteristic" of the products being offered); *Classic Liquor Importers, Ltd. v. Spirits Int'l B.V.*, 201 F. Supp. 3d 428, 452 (S.D.N.Y. 2016) ("Classic Liquor's misuse of the ® symbol in no way relates to an 'inherent quality or characteristic' of its vodka"); *Truck Components, Inc. v. K-H Corp.*, 776 F. Supp. 405, 410 (N.D. Ill. 1991) (statements that defendants were "legally entitled and empowered to design, manufacture and market such products" when they were not allowed to under a covenant not to compete, did not form a basis for liability because "plaintiff has not suggested that the quality of the goods has been misrepresented in any way"). Thus, Nexus cannot meet its burden of pleading, under the Lanham Act, that the shortage statements relate to either party's product.

IV. CONCLUSION

For the above reasons, Defendant's Motion to Dismiss is GRANTED.

SO ORDERED.

/s/ Myong J. Joun
United States District Judge